K061593

510(k) Summary

JUL 12 200

General Information

Classification	Class II, Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Product Cod	GEI
Trade Name	Isolator™ Transpolar™ Pen System
Manufacturer	AtriCure, Inc. 6033 Schumacher Park Drive West Chester, OH 45069
Contact	Elsa Abruzzo Vice President, Clinical and Regulatory Affairs

Intended Use

The Isolator™ Transpolar™ Pen is a sterile, single use electrosurgery device intended to ablate cardiac tissues during cardiac surgery using radiofrequency energy when connected to the Atricure Ablation and Sensing Unit or for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

Predicate Devices

- AtriCure Isolator Transpolar Pen (K050459)
- Medtronic Detect Mapping and Sensing Tool (K040812)
- Viking Diagnostic Electrode Catheter (K971265)
- Estech Cobra System (K051749)

Device Description

The Isolator™ Transpolar™ pen System (Pen) is comprised of the AtriCure® Ablation and Sensing Unit (ASU), Isolator™ Transpolar™ pen, a footswitch, and the ASB1 Source Switch accessory. The Pen is a hand-held, sterile, single patient use electrosurgical instrument intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy. When the Pen is connected to the ASU, either directly or via the ASB1 Source Switch set to the ASU port, the device delivers RF energy for cardiac tissue ablation when the operator presses the Footswitch. When the ASB1 is set to the auxiliary port the pen may be used with a commercially available temporary pacemaker or recorder for temporary cardiac pacing, sensing, recording, or stimulation for the evaluation of cardiac arrhythmias during surgery, based on the function of the device to which it is connected. The two modes of operation, ablation and pacing/sensing cannot be active at the same time.

Materials

All materials used in the manufacture of the Isolator Transpolar Pen System are suitable for this use and have been used in numerous previously cleared products. Testing was conducted in Accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

Summary of Substantial Equivalence

The Isolator Transpolar Pen System is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Atricure, Inc.
c/o Ms. Elsa C. Abruzzo, RAC
Vice President, Regulatory and Clinical Affairs
6033 Schumacher Park Dr.
West Chester OH 45069

Re: K061593
Trade Name: Atricure Isolator Transpolar Pen System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II (two)
Product Code: GEI, DRF
Dated: June 7, 2006
Received: June 8, 2006

Dear Ms. Abruzzo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061593

Device Name: Atricure Isolator Transpolar Pen™

Indications For Use:

The Isolator™ Transpolar™ Pen is intended to ablate cardiac tissues during cardiac surgery using radiofrequency energy when connected to the Atricure Ablation and Sensing Unit or for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061593